K003453

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Fonar Corporation
110 Marcus Drive
Melville, New York 11747-4292

November 3, 2000

510(k) Summary

Submitter Information:

Company: Fonar Corporation
Registration Number 2432211
110 Marcus Drive, Melville, New York 11747-4292

Contact: Luciano Bonanni Executive Vice President
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Device Designation:

Device Name: Sympulse™ Computer System for Fonar MRI Scanners
Common Name: Magnetic Resonance Imaging Scanner (MRI Scanner) Computer System
Classification: System, Nuclear Magnetic Resonance Imaging (NMR/MRI)
Product Code: LNH (formerly 90JAM) Class: 2 Tier: 2
C.F.R. Section 892.1000 Classification Panel: Radiology

Applicable Performance Standards

The Fonar Quality Management System was certified to the standards EN ISO9001, BS EN9001, ANSI/ASQC Q9001-1994 and EN46001:1997. Fonar manufacturing systems were tested to the standards IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-32, IEC 60601-2-33 and DICOM (Digital Imaging and Communication in Medicine).

Predicate Devices:

The Sympulse™ computer system is substantially equivalent to the computer systems in use with existing Fonar MRI systems. It should be noted that while Fonar has presented eight configurations of MRI scanners through the years, there have been only two basic operating systems introduced with those products. The original B3000 and B3000M used the AOS operating system, and all other products to date have used a Unix operating system. In both cases, the major difference in the models was the type or configuration of the magnet, while the computer, software and control electronics was basically the same from system to system.

The Fonar B3000 (P830076), Quad 12000 (K951681)and Fonar 360° (K994287) magnetic resonance imaging scanners were selected as the predicate devices because of their similarities in intended use, magnetic field orientation, construction methods, materials and operating characteristics. They remain substantially equivalent to their previously approved forms.

Description of Device

The Sympulse™ computer system is a system modification/upgrade that replaces the existing VME (Unix) based computer subsystem with a high-speed Windows NT server. This modification includes both hardware and software upgrades. The Sympulse™ hardware consists of a Commercial Off-The-Shelf (COTS) Windows NT server and a Fonar manufactured MRI Controller board packaged in a dual-monitor operator console. The operator console also contains a control panel for power, emergency shutdown, and control of peripheral equipment such as audio player and microphone. The Sympulse™ computer system replaces the previous console, Unix Host computer, Real Time Computer and various VME controller boards. The Sympulse™ software consists of Windows NT application programs ported from Unix and the MRI Controller firmware and device drivers used to control the magnet and acquire scan data.

The Sympulse™ computer system follows the same design principles as our previously approved predicate computer systems. It provides the same functionality as the Quad 12000 (K951681) and FONAR 360° (K994287) computer systems, and partitions that functionality into the same basic architecture that has been used in the previously approved B3000/B3000M (P830076 and supplements), Ultimate 3000 (K910839), Ultimate 7000, Quad 7000 (K940772) and Indomitable (K002490) MRI Scanners. The primary differences of this computer system are it's use of an off-the-shelf server with symmetric microprocessors based on Intel standard superscalar processors running the Windows NT operating system and the consolidation of existing interfaces with the electronics subsystem on the MRI Controller board. It is a significant equivalent of Fonar's currently approved predicate devices.

Sympulse™ Computer System and Predicate Computer System Comparisons

The table below compares and summarizes the common specifications for the predicate devices and the Sympulse™ computer system.

MRI Computer System Comparisons				
Computer Specification	Sympulse™ Computer System	Fonar 360° Computer System	Quad 12000 Computer System	B3000 Computer System
Console	Power switches Emergency Cutoff Patient Intercom Audio player	Power switches Emergency Cutoff Patient Intercom Audio player	Power switches Emergency Cutoff Patient Intercom Audio player	Power switches Emergency Cutoff Patient Intercom
User Interface	Dual Monitor Keyboard Mouse	Dual Monitor Keyboard Mouse	Dual Monitor Keyboard Mouse	Dual Monitor Keyboard Control Knobs Trackball
Computer Platform	Symmetric microprocessors based on Intel standard superscalar processors MRI Controller Board	2 Motorola microprocessors on VME bus boards 4 MRI Controller boards Array Processor	2 Motorola microprocessors on VME bus boards 4 MRI Controller boards Array Processor	DG 4 MHz CPU 12 Controller boards Array Processor
Operating System	Windows NT 4.0	Unix 2.5	Unix 2.5	AOS/VS 7.64
Operating Software	Version 1.0 consisting of: MRI User Interface Control Pulse Sequence Reconstruction Database Server MRI Controller Image display Film DICOM	Release 1.2 consisting of: User Interface Control Pulse Sequence Reconstruction Database Real Time program Image display Film DICOM	Release 1.2 consisting of: User Interface Control Pulse Sequence Reconstruction Database Real Time program Image display Film DICOM	Release 3.2 consisting of: User Interface Control Pulse Sequence Reconstruction Database Image display
Applications Programming language	C++	C++	C	DG Fortran 5

The table shows that the Sympulse™ computer system specifications compare favorably with those of Fonar's previously approved MRI systems.

Indications for Use

The Fonar MRI Systems with Sympulse™ computer systems are indicated for use in producing images of multiple planes in the head and body. These images correspond to the distribution of hydrogen nuclei exhibiting nuclear magnetic resonance (NMR) and depend for their contrast principally upon the NMR parameters T_1 (spin-lattice relaxation time) and T_2 (spin-spin relaxation time) and to a smaller extent on the hydrogen nuclei concentration and flow velocity. As a result of the acquisition and processing of the NMR data, these images display the internal structure of the head and body, and when interpreted by a trained physician, can yield diagnostically useful information.

WARNING: This device is limited by U.S. Federal law to investigational use for indications not in the indications statement.

Under the requirements of the law, the non-indicated applications can be used only under an Institutional Review Board approved protocol for a non-significant risk device or an Investigational Device Exemption application approved by the FDA for a significant risk device. The procedures to be followed, under the sponsorship of Fonar Corporation, are determined by the current guidelines established by the FDA, which should provide the IRB with sufficient guidance to determine the level of risk for an MRI device.

WARNING: U.S. Federal law restricts the sale, distribution and use of this device by or on the order of a physician.

Description of Safety and Substantial Equivalence

MRI effectiveness parameters such as spatial resolution, geometric distortion, specification volume, image uniformity, and slice spacing are unchanged by the new computer system. A series of non-clinical tests and a period of human imaging were performed to demonstrate the safety and effectiveness of the Sympulse™ computer system, and to establish substantial equivalence to the predicate MRI systems. All testing was conducted in accordance with current FDA guidance documents and applicable device regulations. Results from all testing demonstrate substantial equivalence to the predicate devices.

Non-Clinical Testing

Validation testing demonstrates that the Sympulse™ computer system performance meets specification, meets its intended use and is equivalent to the functionality and performance of the existing MRI computer systems. Three complete runs of the validation test procedure were performed by different test teams. The tests are organized into three sections. The MRI user interface section tests the patient management, scan control and image database management. The image display section evaluates screen formats, zooming, windowing, filming, image enhancement, measurements and DICOM. In the third section, all of the scan types (non-oblique, oblique, multi-angle oblique, etc.) are run and evaluated for image quality, orientation, slice presentation, and image labeling.

All of the other parameters identified by the FDA as being pertinent to patient safety are unchanged from the performance reported in the original PMA and it's supplements and subsequent 510(k) submissions.

Clinical Testing

A period of human imaging was performed in accordance with current FDA guidance documents and applicable device regulations that demonstrate the clinical utility of the Sympulse™ computer system. The images provide verification that the Sympulse™ computer system is effective in producing high-quality images with good signal intensity and image uniformity. These clinical tests have provided sufficient experience to demonstrate the substantial equivalency of the Sympulse™ computer system to the previously approved scanners, with no serious malfunctions or adverse effects to patient health or safety reported.

Summary

The material presented within this submission has demonstrated that the Sympulse™ computer system is substantially equivalent to the computer systems and software operating systems for all previously approved Fonar MRI magnets under their current conditions for intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2001

Luciano Bonanni
Executive Vice President
Fonar Corporation
110 Marcus Drive
Melville, New York 11747-4292

Re: K003453
Sympulse™ Computer System for Fonar MRI Scanners
Dated: November 3, 2000
Received: November 7, 2000
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Bonanni:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INDICATIONS FOR USE

Applicant: FONAR CORPORATION
510(k) Number (if known): K00 3453
Device Name: Sympulse™ Computer System for Fonar MRI Scanners

Indications For Use:

The Sympulse™ Computer System for Fonar MRI Scanners is indicated for use in producing images of multiple planes in the head and body. These images correspond to the distribution of hydrogen nuclei exhibiting nuclear magnetic resonance (NMR) and depend for their contrast principally upon the NMR parameters T_1 (spin-lattice relaxation time) and T_2 (spin-spin relaxation time) and to a smaller extent on the hydrogen nuclei concentration and flow velocity. As a result of the acquisition and processing of the NMR data, these images display the internal structure of the head and body, and when interpreted by a trained physician, can yield diagnostically useful information.

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WARNING: U.S. Federal law restricts the sale, distribution and use of this device by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER LINE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003453